



BILLING CODE: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Activities Deemed Not to Be Research: Public Health Surveillance, 2018

Requirements

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled, “Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements.”

DATES: Submit written comments by [INSERT 30 DAYS FROM PUBLICATION OF FR NOTICE].

ADDRESSES: Submit written requests for a single copy of the draft guidance document entitled “Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements,” to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-453-6909. See the **SUPPLEMENTAL INFORMATION** section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OS-OPHS-2018-0015 (Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements), by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the docket ID number and click on “Search.” On the next page, click the “Comment Now” action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; email Irene.Stith-Coleman@hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled “Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements.” This guidance document applies to activities that are conducted or supported by HHS. It is intended to help entities determine whether a planned activity constitutes a public health surveillance activity deemed not to be research under the 2018 Requirements (the revised subpart A of 45 CFR part 46, effective July 19, 2018). The draft guidance document, when finalized, will represent OHRP’s current thinking on this topic. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance document.

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP’s website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Dated: November 8, 2018.

Julie Kaneshiro,

Deputy Director,

Office for Human Research Protections.

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